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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,047	08/26/2003	Bill H. McAnalley	23100.61	3228

27683 7590 12/31/2007  
HAYNES AND BOONE, LLP  
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Suite 3100  
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EXAMINER
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MOSS, KERI A

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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12/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/648,047	<b>Applicant(s)</b> MCANALLEY ET AL.	
	<b>Examiner</b> Keri A. Moss	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8, and 10-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Amendment filed September 27, 2007 is hereby acknowledged.  
Claims 1, 5, 8, and 10-22 are pending.

### ***Response to Amendment***

2. The rejection under Packer et al has been withdrawn in light of applicants' amendments and arguments.
3. The rejection under Fleischner has been maintained and new grounds of rejection under Howard et al. (USP 6,642,277) has been added in light of applicant's amendments and arguments.
4. The Examiner notes that the amendments narrowed the scope of the claims in such a way that required the Examiner to interpret each of bush plum, green tea extract and grape skin extract to an extent not required by the previous claims. This is because the previous claims comprised one of bush plum, green tea extract, grape skin extract or a mixture thereof, whereas the newly amended claims comprise all three components.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims **1, 5, 8, and 10-22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. It is unclear exactly what chemical species applicants are claiming with the terms "bush plum", "green tea extract" and "grape skin extract". The specification does not specify exactly what chemicals are included in these descriptions. Reading the claims in light of the specification p.12, it appears that applicants are definitively claiming for these limitations, the following known chemical species: 1) bush plum – vitamin C, 2) green tea extract – polyphenols, and 3) grape skin extract – polyphenols. No further detail regarding the type of polyphenols are given.

8. It is unclear what parts of the bush plum applicants are claiming with the limitation "bush plum." While applicants are claiming "bush plum" in the antioxidant composition, the specification on page 12 tells us that it is not the entire bush plum, but only the pulp and skin that is in the composition.

#### ***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims **1, 5, 8, and 10-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard et al (USP 6,642,277). Howard discloses an antioxidant composition comprising a flavonoid consisting of a flavone (abstract) such as quercetin, kaempferol or myricetin (column 1 lines 66- column 2 line 12); a mixture of at least two

forms of vitamin E such as alpha tocopherols and other active tocopherols (column 9 lines 34-57); antioxidant extracts of bush plum, such as vitamin C; antioxidant extracts of green tea, such as polyphenols (column 9 lines 34-57); and antioxidant extracts of grape skin, such as polyphenols (column 9 lines 34-57). Howard recommends that the composition comprise at least 25% w/w polyphenols, or secondary ingredients (columns 5 and 6). The composition may comprise a carrier comprising aloe vera (paragraph bridging columns 8 and 9).

Howard does not teach a ratio of flavonoid to mixture of vitamin E forms as 40/60 to 90/10 percent by weight.. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) teaches that optimization of a result-effective variable is ordinarily within the skill of one in the art. A result-effective variable is one that has well-known and expected results.

The selection of percentage by weight of any ingredient in the antioxidant composition are result effective variables. Varying the percentage by weight of any ingredient has the well-known and expected result of producing the desired result of the ingredient (i.e. improved cardiovascular health) in a composition of a varied size. Therefore, it would have been obvious to one of ordinary skill in the art to meet the percentage by weight requirements of claimed ingredients such as flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, green tea extract and a carrier such as aloe vera gel extract by modifying Howard and selecting the flavonoid/vitamin E mixture percentage by weight of 40/60 to 90/10 in order to control for the desired result and control the size of the composition.

11. Claims **1, 5, 8, and 10-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischner (USP 6,291,533). Fleischner teaches an antioxidant composition comprising a flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, Vitamin C, polyphenols green tea extract and a carrier such as aloe vera gel extract (columns 7-8). Fleischner does not teach a ratio of flavonoid to mixture of vitamin E forms as 40/60 to 90/10 percent by weight. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) teaches that optimization of a result-effective variable is ordinarily within the skill of one in the art. A result-effective variable is one that has well-known and expected results.

The selection of percentage by weight of any ingredient in the antioxidant composition are result effective variables. Varying the percentage by weight of any ingredient has the well-known and expected result of producing the desired result of the ingredient (i.e. improved cardiovascular health) in a composition of a varied size. Therefore, it would have been obvious to one of ordinary skill in the art to meet the percentage by weight requirements of claimed ingredients such as flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, green tea extract and a carrier such as aloe vera gel extract by modifying Fleischner and selecting the flavonoid/vitamin E mixture percentage by weight of 40/60 to 90/10 in order to control for the desired result and control the size of the composition.

### ***Response to Arguments***

12. Applicant's arguments filed September 27, 2007 have been fully considered but they are not persuasive. Applicants' amendment to claim 1 narrowed the scope of the claims as a whole in a way that required a composition requiring all three of bush plum, green tea extract and grape skin extract; whereas, the previous claims required only one of these. After interpretation of these limitations of the claims in light of the specification, the Examiner finds that these limitations represent the chemicals known by the applicants to have antioxidant activity. Reading the claims in light of the specification p.12, it appears that applicants are definitively claiming for these limitations, the following known chemical species: 1) bush plum – vitamin C, 2) green tea extract – polyphenols, and 3) grape skin extract – polyphenols. No further detail regarding the type of polyphenols are given. In light of this interpretation of the claims, the Examiner believes that the prior art references of Fleischner and Howard disclose the composition as claimed under an obviousness theory.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

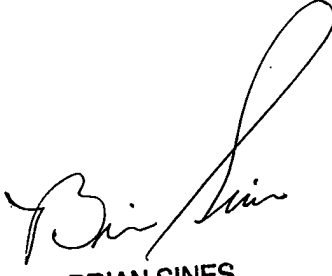


Application/Control Number:  
10/648,047  
Art Unit: 1797

Page 8

Keri A. Moss  
Examiner  
Art Unit 1797

12/21/07



**BRIAN SINES**  
**PRIMARY EXAMINER**